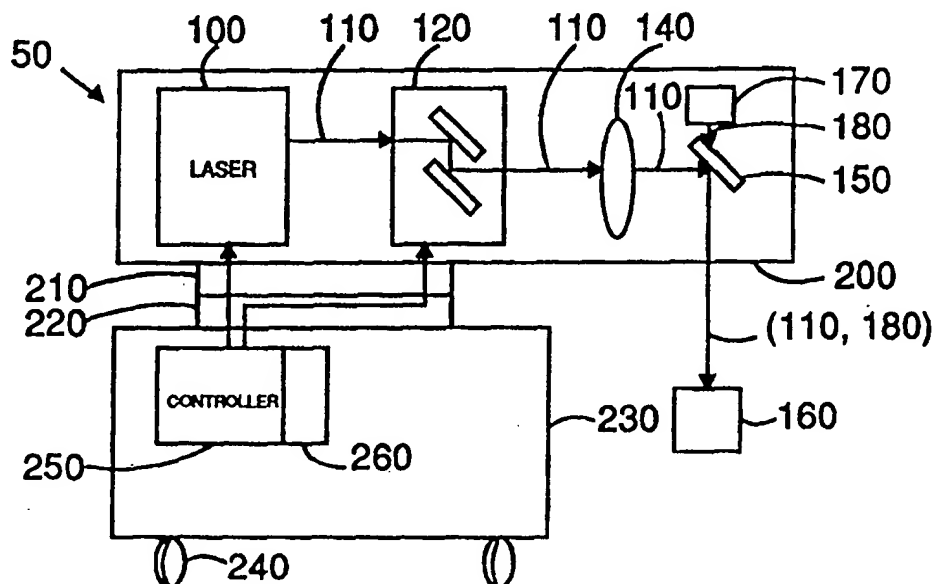


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61N 5/02		A1	(11) International Publication Number: WO 98/18522
			(43) International Publication Date: 7 May 1998 (07.05.98)
(21) International Application Number: PCT/US97/19241 (22) International Filing Date: 28 October 1997 (28.10.97) (30) Priority Data: 60/029,790 28 October 1996 (28.10.96) US (71) Applicant: LASERSIGHT TECHNOLOGIES, INC. [US/US]; Suite 160, 12449 Science Drive, Orlando, FL 32826 (US). (72) Inventors: TANG, Fuqian; 10629 Via Del Sol, Orlando, FL 32817 (US). HAN, Xiaofeng; 13541 Blue Water Circle, Orlando, FL 32828 (US). (74) Agent: BOLLMAN, William, H.; Farkas & Manelli PLLC, Suite 700, 1233 20th Street, N.W., Washington, DC 20036 (US).		(81) Designated States: AU, CA, IL, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.	

(54) Title: COMPOUND ASTIGMATIC MYOPIA OR HYPEROPIA CORRECTION BY LASER ABLATION



(57) Abstract

An apparatus (50) is provided for performing corneal refractive surgery by ablating a portion of a corneal surface of any eye. The apparatus includes a pulsed laser (100) for producing a pulsed output beam of light. A scanning mechanism (120) scans the output beam (110), and the output beam is operatively associated with the scanning mechanism such that the output beam may be scanned over a predetermined surface defined by a mathematically derived ablation layer boundary curve for each ablation layer. A controller (250) is operatively associated with the scanning mechanism so as to deliver output beams to the predetermined surface (160) such that center points of output beams may be disposed within the ablation layer boundary curve, on the ablation layer boundary curve, and outside, but within a predetermined distance from a nearest point on the ablation layer boundary curve so as to integrate the edges of the ablation layer boundary curve to more closely correspond to the desired ablated shape.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

COMPOUND ASTIGMATIC MYOPIA OR HYPEROPIA CORRECTION BY LASER ABLATION

5 This application claims priority from U.S. Provisional application
No. 60/029,790, filed on October 28, 1996, the specification of which is
incorporated in its entirety herein.

BACKGROUND OF THE INVENTION

Field of the Invention

10 This invention relates to an apparatus for refractive correction
utilized to ablate corneal tissue to reshape the corneal surface, and more
particularly, to apparatus for corneal re-profiling by laser ablation for
correction of myopia, hyperopia, astigmatic myopia and astigmatic
hyperopia conditions.

Description of Related Art

15 With reference to FIG. 1, a schematic illustration of a normal eye
is shown, wherein light rays 10 pass through the cornea 12 of eye 14
through lens 16 to the retina 18. In a normal eye, the focal point 20 of the
light rays occurs on the retina 18 for normal vision.

20 Common vision defects occur when the focal point 20 is not
disposed on the retina 18. For example, as shown in FIG. 2, myopia
occurs when the focal point 20 is disposed in front of the retina 18.
Myopia may be corrected as shown in FIG. 3 by using conventional
methods by ablating tissue 24 of the cornea 12 so as to increase the
radius of curvature of cornea 12 to shift the focal point 20 to be on the
25 retina 18.

With reference to FIG. 4, hyperopia occurs when the shape of the cornea does not permit the light rays 10 to focus on the retina 18. Instead, the focal point 20 of the light rays 10 in an eye suffering from hyperopia is disposed behind the retina 18. As shown in FIG. 5, hyperopia can be corrected by ablating tissue 24 of the cornea 12 so as to decrease the radius of curvature of the center of the cornea 12, shifting the focal point 20 to be on the retina 18.

FIGS. 6 and 6A illustrate myopic astigmatism. As shown in FIG. 6, x-direction light rays 10' and y-direction light rays 10" pass through the cornea 12 and lens 16 to the retina 18. However, due to the shape of the cornea 12, the x-direction light rays 10' focus at focal point 20', while the y-direction light rays 10" focus at focal point 20" in front of the retina 18, causing vision to be blurred. FIG. 6A is a three-dimensional illustration of the light rays 10' and 10" passing through the cornea 12 and showing the location of the focal points 20' and 20". Myopic astigmatism can be corrected by re-profiling the surface of the cornea 12 to obtain a single focal point on the retina 18. It can be appreciated that in hyperopic astigmatism, the focal points 20' and 20" of the x-direction and y-direction light rays, respectively, are behind the retina. Hyperopic astigmatism may also be corrected by corneal re-profiling.

When correcting conditions such as, for example, myopia, hyperopia and/or astigmatism, the eye may be ablated in thin layers by an excimer laser or the like to achieve the desired correction. For simple myopic correction, the shape of each layer of the ablation is represented by the equation for a circle. Parabolic, spherical or other mathematical models could be used. For a small laser beam to ablate each layer of the

corneal tissue, the laser beam must be scanned across the surface of the eye, inside of and on the curve defining the zone of ablation. Many approaches can be used to scan each layer. The scanning process may be defined as linear, circular, random multi-beam, or other useable method.

However, when employing a mathematically modeled curve to define a each layer of ablation in performing laser vision corrections, and when the center of each laser pulse is positioned inside of or at the boundary of the curve, the effective ablation area for each layer may be smaller than that defined by the actual curve modeled because of the incremental movement of the laser. Thus, the correction may not be as effective as theorized.

Accordingly, there is a need to provide an apparatus that controls laser pulse center point positions effectively throughout a layer of ablation.

SUMMARY OF THE INVENTION

It is an object of the invention to fulfill the need referred to above. In accordance with the principles of the present invention, this object is obtained by providing an apparatus and method for performing corneal refractive surgery by ablating a portion of a corneal surface of an eye. The apparatus includes a pulsed laser for producing a pulsed output beam of light. A scanning mechanism scans the output beam, and the output beam is operatively associated with the scanning mechanism such that the output beam may be scanned over a predetermined surface

defined by a mathematically derived curve. Focusing structure focuses the output beam onto the predetermined surface to a predetermined, generally fixed spot size. A controller is operatively associated with the scanning mechanism so as to deliver output beams to the predetermined surface such that center points of output beams may be disposed within an ablation layer defined by the curve, on the boundary of the ablation layer, and at certain locations outside of the ablation layer so as to ablate the predetermined surface substantially corresponding to an area enclosed by the curve. A method of controlling the above described apparatus is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Features and advantages of the present invention will become apparent to those skilled in the art from the following description with reference to the drawings, in which:

FIG. 1 is a schematic illustration of a normal eye showing light passing through the cornea and lens and focusing at the retina;

FIG. 2 is a schematic illustration of an eye having a myopia condition wherein the focal point is disposed internally within the eye and not at the retina;

FIG. 3 is a schematic illustration of the eye of FIG.2 after ablation of the cornea thereby correcting the myopia condition;

FIG. 4 is a schematic illustration of an eye having a hyperopia condition wherein the focal point occurs outside of the eye;

FIG. 5 is a schematic illustration of the eye of FIG. 4 after ablation of the cornea thereby correcting the hyperopia condition;

5 FIG. 6 is an illustration of an eye having myopic astigmatism wherein x-direction light rays and y-direction light rays focus at separate points within the eye and not at the retina;

FIGS. 6A is a three dimensional schematic illustration of the x and y direction light rays entering the eye of FIG. 6;

10 FIGS. 7A and 7B are illustrations of conventional scanning patterns for a linear scan and a circular scan approach, respectively, for the treatment of myopia;

FIG. 8A and 8B are illustrations of conventional scanning patterns for a linear scan and a circular scan approach, respectively, for the
15 treatment of astigmatic myopia;

FIG. 8A(1) is an enlarged view of the encircled portion A of FIG. 8A;

FIG. 9 is an illustration of an ablation if it were a flat surface for an eye having a conventional circular ablation layer to correct for simple
20 myopia;

FIG. 10 is an illustration of an ablation if it were a flat surface of an eye having a conventional cylindrical-like ablation layer to correct for astigmatism;

5 FIG. 11 is an illustration of a corneal surface of an eye having a conventional oval pattern ablation layer to correct for astigmatism in addition to simple myopia;

10 FIG. 12 is an illustration of a scanning pattern for a linear scan approach of the invention having random starting laser center points and which includes laser center points that are outside of but close to the boundary of the ablation layer;

FIG. 13 is a illustration of a scanning pattern for a circular scan approach according to the invention having a random center location and including laser center points that are outside of but close to the ablation layer;

15 FIG. 14 is a schematic illustration of an apparatus for re-profiling a surface of the eye, provided in accordance with the invention;

FIG. 15 is a side view of a cornea after conventional refractive surgery; and

20 FIG. 16 is a side view of a cornea after refractive surgery according to the invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EXEMPLARY EMBODIMENTS

5 To understand correction of a corneal defect, theoretical background is as follows.

If $Z_1(x,y)+c_1$ describes the initial corneal surface of an eye, and $Z_2(x,y)+c_2$ describes the corneal surface after ablation, then the ablation depth $D(x,y)$ is defined by:

$$10 \quad D(x,y) = Z_1(x,y) - Z_2(x,y) + c. \quad (\text{Equation 1})$$

In Equation 1, the xy -plane is parallel to the tangential plane at the apex of the eye, and the origin of the xy -plane is the center point of the ablation. Constants c_1 and c_2 are related to the origin of the coordinate system. The constant c in Equation 1 is dependent on the zone size (or
15 depth) of ablation. Constant c may be computed from a set of default conditions.

If it is assumed that the eye is ablated by thin layers by an excimer laser or the like to achieve the desired correction, and the thickness of each thin layer is Δ , the ablation for the n th layer is, following Equation 1:

$$20 \quad n\Delta = Z_1(x,y) - Z_2(x,y) + c. \quad (\text{Equation 2})$$

No matter how the eye surface is modeled, for simple myopic correction the shape of each layer of ablation is represented by the equation for a circle. Simple myopic correction requires a symmetric model of the eye surface and each cross-section, or layer, is a circle as represented by
25 Equation 2. Also, the equations for $Z_1(x,y)$ and $Z_2(x,y)$ depend on how the

surface of the eye is modeled. Parabolic, spherical, or other models could be used. For example, if the eye surface is considered to be a symmetric paraboloid before and after the corrective surgery, $Z_1(x,y)$ and $Z_2(x,y)$ may be represented by the following equations:

$$Z_1(x,y) = -\frac{1}{2R_1}(x^2 + y^2) + c_1.$$

$$Z_2(x,y) = -\frac{1}{2R_2}(x^2 + y^2) + c_2. \quad (\text{Equation 3})$$

The new equation for the depth of ablation can now be redefined as

$$D(x,y) = -\frac{1}{2}\left(\frac{1}{R_1} - \frac{1}{R_2}\right)(x^2 + y^2) + \frac{Z_0^2}{8}\left(\frac{1}{R_1} - \frac{1}{R_2}\right) \quad (\text{Equation 4})$$

where R_1 is the initial radius of curvature of the eye at the apex, R_2 is the radius of curvature after the surgery, and Z_0 is the ablation zone diameter. The constant c from Equation 2, which is also the total depth of ablation at the center (0,0), is represented as the second term on the right hand side of Equation 4.

Another example for the model of the eye surface is a spherical model both before and after ablation. In this case, the following equations are developed:

$$Z_1(x,y) = \sqrt{R_1^2 - x^2 - y^2} + c_1,$$

$$Z_2(x,y) = \sqrt{R_2^2 - x^2 - y^2} + c_2, \quad (\text{Equation 3'})$$

$$D(x,y) = \sqrt{R_1^2 - x^2 - y^2} - \sqrt{R_2^2 - x^2 - y^2} + \sqrt{R_2^2 - \frac{Z_0^2}{4}} - \sqrt{R_1^2 - \frac{Z_0^2}{4}}.$$

(Equation 4'')

However, no matter how the eye surface is modeled, Equation 1 can be simplified with a parabolic equation with a certain amount of error. Equation 4 is already a parabolic equation for the parabolic model. For a spherical model, Equation 1 can be simplified by approximating Equation 4' with the following:

$$D(x,y) \approx D_0 - \frac{1}{2} \left(\frac{1}{R_1} - \frac{1}{R_2} \right) (x^2 + y^2) \quad (\text{Equation 5})$$

where D_0 is the total depth of ablation, given by

$$D_0 = \sqrt{R_2^2 - \frac{Z_0^2}{4}} - \sqrt{R_1^2 - \frac{Z_0^2}{4}} - (R_2 - R_1)$$

Since Equation 2 defines the equation for a circle, the layered ablation process is very easy to control. Since the model used for simple myopia must be radially symmetrical, it can be simplified from three dimensional to two dimensional, as shown by Equations 3', 4' and 5. Astigmatic myopia is a different case because the ablation zone is not circular.

For a small laser beam to ablate each layer of the corneal tissue, the laser beam must be scanned across the surface of the ablation layer of the eye. The scanning process may be linear, circular, multibeam, or any other usable method. The point-by-point computation of the ablation points within the ablation layer is relatively straight forward because the ablation zones for each ablation layer for the correction of simple myopia are defined by circles. A simple ablation method can be designed following the symmetry of each layer. The laser is focused at points following parallel lines (linear scan) across the layer, or can follow concentric circle patterns (circular scan), spiral patterns (spiral scan), or other approaches.

FIG. 7A illustrates an example of a conventional linear scan approach and FIG. 7B illustrates an example of a conventional circular scan approach. Each point only indicates the center of a laser beam, not the size of the laser beam. It can be appreciated from FIGs. 7A that the conventional linear scan pattern is roughly symmetric about a line which is positioned perpendicular to and disposed through the center of the circular layer. The conventional circular scan, on the other hand, is symmetric about the center of the ablation layer.

The most general case is when the initial and final corneal surfaces are modeled asymmetrically (such as an ellipsoid) about the center of treatment. In such general cases, both $Z_{g1}(x,y)$ and $Z_{g2}(x,y)$ which define the initial and final surfaces, respectively, are complicated expressions for complicated surface shapes. The new ablation depth equation is represented as:

$$D_g(x,y) = Z_{g1}(x,y) - Z_{g2}(x,y) + c \quad (\text{Equation 6})$$

Similar to Equation 2 each layer of ablation is defined as:

$$n\Delta = Z_{g1}(x,y) - Z_{g2}(x,y) + c. \quad (\text{Equation 7})$$

5 Unlike Equation 2, however, Equation 7 is not an equation for a circle. It is an enclosing curve which more closely resembles an ellipse. Equation 7 defines the ablation layer as an oval layer for the more general case. It can become considerably more complex in the case where x and y are substituted by expressions in terms of other variables. This occurs, for example, when the linear scan is rotated for each layer so that x and y are expressed by two other variables of another orthogonal basis coordinate system. It is difficult to plot the shape of each layer to be ablated without significant computation and time. Even if the shape is determined by computation, it is still difficult to control the ablation because of the time required for the computations, and because the process is not symmetric for either the linear or circular scan, as shown in FIGS. 8A and 8B. It is therefore difficult to devise a method to control the ablation.

If the eye surface is modeled for astigmatic myopia before and after surgery as asymmetric parabolic surfaces, the following equations are developed:

$$Z_{g1}(x,y) = -\frac{1}{2} \left(\frac{x^2}{R_{1x}} + \frac{y^2}{R_{1y}} \right) + c_1$$

5

$$Z_{g2}(x,y) = -\frac{1}{2}\left(\frac{x^2}{R_{2x}} + \frac{y^2}{R_{2y}}\right) + c_2.$$

(Equation 8)

Therefore, Equations 6 and 7 become:

10

$$D(x,y) = -\frac{1}{2}\left(\frac{x^2}{R_{1x}} + \frac{y^2}{R_{1y}}\right) + \frac{1}{2}\left(\frac{x^2}{R_{2x}} + \frac{y^2}{R_{2y}}\right) + c$$

15

(Equation 9)

and

20

$$n\Delta = -\frac{1}{2}\left(\frac{x^2}{R_{1x}} + \frac{y^2}{R_{1y}}\right) + \frac{1}{2}\left(\frac{x^2}{R_{2x}} + \frac{y^2}{R_{2y}}\right) + \frac{Z_y^2}{8}\left(\frac{1}{R_{1y}} - \frac{1}{R_{2y}}\right)$$

25

(Equation 10)

where the R 's represent the radii of curvature of the eye, the subscripts 1 and 2 specify before and after the ablation, respectively, and x , y , and z specify the coordinates along the x -axis, y -axis, and z -axis, respectively. It is assumed that the radius of curvature before the ablation is smallest along the x -axis, and largest along the y -axis. Z_y is the ablation zone size in the y direction. The model is not radially symmetric, but it is symmetric across the axes.

35 The preferred model used in the exemplary embodiment of the present invention models the eye surfaces before and after surgery as toruses, and are represented by the following equations:

$$Z_{g1}(x,y) = \sqrt{\left(\sqrt{R_{1x}^2 - x^2} + R_{1y} - R_{1x}\right)^2 - y^2} + c_1,$$

5 and

10 (Equation 8')
$$Z_{g2}(x,y) = \sqrt{\left(\sqrt{R_{2x}^2 - x^2} + R_{2y} - R_{2x}\right)^2 - y^2} + c_2.$$

Equations 6 and 7 now become:

15
$$D(x,y) = \sqrt{\left(\sqrt{R_{1x}^2 - x^2} + R_{1y} - R_{1x}\right)^2 - y^2} - \sqrt{\left(\sqrt{R_{2x}^2 - x^2} + R_{2y} - R_{2x}\right)^2 - y^2} + c$$

and

(Equation 9')

20
$$n\Delta = \sqrt{\left(\sqrt{R_{1x}^2 - x^2} + R_{1y} - R_{1x}\right)^2 - y^2} - \sqrt{\left(\sqrt{R_{2x}^2 - x^2} + R_{2y} - R_{2x}\right)^2 - y^2}$$

25
$$+ \sqrt{R_{2y}^2 - \frac{Z_y^2}{4}} - \sqrt{R_{1y}^2 - \frac{Z_y^2}{4}}$$
 (Equation 10')

30

The model used for astigmatic myopia can be readily applied to simple myopia. In other words, simple myopia is merely a special case of astigmatic myopia, wherein $R_x = R_y$, reducing Equations 10 and 10' to the equations of circles. Other models such as ellipsoid eye surfaces may

35

be used to model the surface of the eye requiring treatment for astigmatic myopia, and the mathematical treatment is similar.

To correct astigmatic myopia or astigmatic hyperopia, the laser ablation of the cornea must make different diopter changes in different
5 directions. This way, the patient becomes non-astigmatic, without myopia or hyperopia.

In the case of astigmatic myopia with the x-axis as the steeper axis, the ablations, when illustrated on a flat surface, are shown in two steps
10 in FIGS. 9 and 10. A first series of circular ablation layers correct for the myopia (FIG. 9) or hyperopia and an *additional* series of cylindrical-shape or other ablation layers (FIG. 10) correct the astigmatism. In this approach, the total depth of the ablation in the center is the sum of the two corrections, and the tissue removed is also the sum of the two
15 corrections. Unfortunately, the amount of tissue removed and the amount of time of the ablation are large. Clearly, this two step approach for correcting astigmatic myopia is not desirable, but until now was a practical answer to the problem solved by the present invention. For example, high diopter patients require deep ablation. In this instance, this two step
20 approach can be severely limited due to the total ablation depth required. As a result, the patient may not be treated fully for both the astigmatism and the myopia or hyperopia.

A new mathematical approach to control the ablation of corneal tissue for the correction of both the astigmatism and the myopia and
25 hyperopia condition has been known to exist. However, as will be shown, this approach continues to require the solving of complicated equations, requiring too much time and computational power.

To illustrate this mathematical approach, the simple myopia case is considered once again. As discussed previously, Equation 2, describes a single n th layer ablation which can be reduced to a circle equation of the form:

$$R^2 - (x^2 + y^2) = 0 \quad (\text{Equation 11})$$

where R is the radius. By slightly modifying Equation 11, the following relationship is determined :

$$x^2 + y^2 \leq R^2. \quad (\text{Expression 12})$$

Next, it is required under this approach that the laser energy distribution satisfy Equation 12 by simply stating that all the laser energy has to be on or inside the area defined by the circle. For scanning ablation, this means that each scan point (x,y) is checked by using Expression 12 during the surgery to verify its inclusion or exclusion as a point to be ablated. Using this known technique, all points outside of the circle of Equation 12 are excluded as an ablation point. during the surgery.

Expression 12 eliminates the need to solve for complicated Equations 7, 10, or 10' such that y is a function of x . Instead, the laser power distribution may be represented by

$$n\Delta - Z_{g1}(x,y) + Z_{g2}(x,y) - c \leq 0 \quad (\text{Expression 13})$$

or other, similar forms for different eye surface models. This means that the laser pulses will be directed only within and on the ellipse-like enclosing curve.

This newer procedure realizes the different diopter (curvature) changes in the x-axis and y-axis to correct for astigmatism and myopia or hyperopia together, without requiring the additional cylindrical ablation shown in FIG. 10.

5 Reduction of the diameter in the x-axis direction at each and every layer depth to end up with an oval pattern is shown in FIG. 11. With the diameter squeezed in a certain mathematically determined fashion at different depths of ablation, the diopter change on the corneal surface will be more in the x-axis direction than in the y-axis direction. This process
10 corrects astigmatic myopia.

 In review, with the above procedure shown with respect to FIGs. 8A, 8B, and 11, the curvature change will be larger in the x-axis direction than in the y-axis direction. The total depth of ablation is the same as that of the counterpart ablation for simple myopia correction. The amount of
15 tissue removal is less than that of the counterpart ablation for simple myopia correction, due to the reduced ablation dimension in the x-axis direction. The amount of tissue removal is also far less than that of the two-step procedure discussed above and shown in FIGS. 9 and 10.

 The x-axis and y-axis have been arbitrarily chosen in this work.
20 Thus, the procedure described here is applicable to symmetric astigmatic myopia/hyperopia corrections at any angle.

 In accordance with the invention, it is preferable to use the torus model for the eye surface and consider the layered scan; i.e., Expressions

9', 10' and 13. Expression 13 is used since it is much easier to solve than Equation 10'. It is noted that the effective ablation area for each layer might be smaller than the enclosed area by the solid curve. For example, since only laser pulse center points 34 (FIGS. 8A, 8B) that fall within or
5 on the boundary of the curve 36 are used during the conventional surgery, corneal material near but outside the curve 36 may not be ablated. Depending on the distance d between each ablation point 34, on the same line scans the last point ablated may be just less than the distance d as shown in FIG. 8A(1). As shown in FIG. 8A(1), although the
10 ablation layer boundary curve 36 defines the desired area for ablation, the actual ablation layer boundary 36 is somewhat smaller. Thus, the area actually ablated 36a is smaller than the entire area enclosed by the curve 36. The resulting corneal surface alteration may not be as precisely the same as predicted by the math model. Thus, with reference to FIG. 15,
15 the cornea 12 may be ablated which results in wall surface 30, instead of a theoretical wall surface 32. An important aspect of the present invention is to provide a controllable apparatus and process to approach the theoretical ablation layer curve 36 more closely.

In accordance with the invention, Expression 13 is modified slightly
20 so that the laser center points near but outside the curve 36 are included in the scan if they are close enough to the boundary, e.g., within $d/2$, where d is the distance between scan points 34.

To illustrate this point, consider the linear scan situation (rather
25 than the circular scan). If the linear scan is taken along the direction of a p -axis (major axis), and a q -axis (minor axis) is orthogonal to the p -axis, then the transformations to x - y coordinates are given by:

$$x = x(p,q), \quad y = y(p,q). \quad (\text{Equation 14})$$

The exact expressions for $x(p,q)$ and $y(p,q)$ depend on the relative positions of the xy and pq coordinate systems. Expression 13 now becomes:

$$n\Delta + F(p,q) - c \leq 0 \quad (\text{Expression 15})$$

where

$$F(p,q) = -Z_{g1}(x(p,q), y(p,q)) + Z_{g2}(x(p,q), y(p,q)). \quad (\text{Expression 16})$$

Expression 15 can be substituted by the following four expressions:

$$n\Delta + F(p + \delta, q + \delta) - c \leq 0 \quad (\text{Expression 15a})$$

$$n\Delta + F(p + \delta, q - \delta) - c \leq 0 \quad (\text{Expression 15b})$$

$$n\Delta + F(p - \delta, q + \delta) - c \leq 0 \quad (\text{Expression 15c})$$

$$n\Delta + F(p - \delta, q - \delta) - c \leq 0 \quad (\text{Expression 15d})$$

If it is required that each laser pulse position satisfy at least one of the four Expressions 15a-15d to be included in the scan, then not only points inside and on the curve defining the ablation layer, but also points that are outside the generally oval-shaped ablation layer by approximately a distance δ are nevertheless included in the predetermined surface layer to be ablated. Thus, according to the present invention, the laser beam is sometimes focused on points outside the defined ablation layer area. This provides an "integration" over the curve 36 to provide a total ablation which more closely approaches the theoretically desired resulting corneal shape.

It has been determined that a reasonably good choice for δ is half the scanning step size d . Therefore, points that are close enough to the boundary curve (i.e., within δ in the p or q directions) are included in the ablation, and points that are too far away from the curve (i.e., greater than δ in both the p and q directions) are omitted from the ablation. Therefore, the effective ablated area is closer to the area enclosed by the curve 36.

FIG. 16 depicts the corneal shape resulting, for ablation of the points outside but close to the ablation layer. As shown, since laser pulse center points outside the boundary of the curve are included in the ablation, wall 30 substantially coincides with theoretical wall 32 and results in a smoother, less jagged surface.

The principles of the present invention can be expanded using other techniques. For example, a linear scan with random starting points is shown in FIG. 12. Only the points that satisfy any one of the Expressions 15a-15d are included in the ablation, as shown in FIG. 12. The points outside the ablation layer curve 36 are depicted by dots 34, and the points outside but near enough to the ablation layer curve 36 are depicted by dots 38 enclosed by circles. Using a random start technique, the starting point for each scan line 40 is not regular, thus randomizing the scan. It is noted again that the laser pulse points 34 and 38 indicate the center of the laser beam and in actual practice the laser pulses have a predetermined spot size and overlap.

Another technique augmenting the application of the present invention is the use of a circular scan with a random center point, as shown in FIG. 13. The center of the circular scan can be any point other than the symmetrical center of the ablation layer, using this technique.

The center of each layer to be ablated is placed randomly in the layer to minimize the accumulative effect when many layers are ablated. Again, points 34 within the ablation layer curve 36 are included in the scan together with encircled points 38 which are those points outside but near
5 enough to the curve 36.

Referring to FIG. 14, a refractive laser system 50 provided in accordance with the present invention is shown which is capable of performing the scan and ablation defined above. The system 50 comprises a laser 100 having UV (preferably 193-220 nm) or IR (0.7-3.2
10 μm) wavelength to generate a beam 110. A scanning device 120 capable of controllability changing the incident angle of the laser beam 110 passes the angled beam 110 to the focusing optics 140, onto a reflecting mirror 150, and onto target 160. The laser beam 110 preferably has an energy level less than 10 mJ/pulse. The target 160 is the cornea of an
15 eye.

An aiming system 170 has a visible wavelength light beam (preferably from a laser diode or He-Ne laser) 180 adjusted to be co-linear with the ablation laser beam 110 to define the normal incident angle. The
20 basic laser head 200 is steered by a motorized stage for X and Y horizontal directions 210 and the vertical (height) direction 220 which assures the focusing beam spot size and concentration of the beam onto the cornea. The system 50 has a control panel 230 including a controller 250 for controlling the laser 100 and for controlling scanning mechanism
25 120 for controlling the angle of the beam 110, and for controlling all other aspects of system 50. Wheels 240 are provided to make the system 50 portable.

The basic laser head 200 and control panel 230 are of the type

disclosed in U.S. Patent No. 5,520,679, the content of which is hereby incorporated by reference into the present specification. However, in accordance with the invention, the controller 250 in the form of a microprocessor, digital signal processor, or microcontroller, includes in
5 program memory 260 the expressions necessary to control the scanning mechanism 120 to ensure that the laser pulse center point positions may occur at locations inside, on, and outside of but substantially near the boundary of the mathematically defined ablation layer curve 36 (FIGs. 12, 13). Thus, the memory 260 includes the functions of Expressions 15a-
10 15d defined above. The controller 250 also permits the scan to start in a random manner (linear scan) using a random center point (circular scan), or any other augmenting technique.

It can be appreciated by employing the apparatus of the invention having the inventive models, myopia, hyperopia, astigmatic myopia and
15 astigmatic hyperopia conditions may be rectified in a manner that corresponds more closely to a mathematically defined curve selected to model the surface of the cornea to be ablated. This is possible since certain laser center points outside of the curve boundary are selected during ablation.

It has thus been seen that the objects of this invention have been
20 fully and effectively accomplished. It will be realized, however, that the foregoing preferred embodiments have been shown and described for the purposes of illustrating the structural and functional principles of the present invention, as well as illustrating the methods of employing the
25 preferred embodiments and are subject to change without departing from such principles. Therefore, this invention includes all modifications encompassed within the spirit of the following claims.

What is claimed is:

1. A method of ablating a surface area, comprising:
 - defining an ablation layer area;
 - centering a laser beam at a first plurality of ablation points within said ablation layer area;
 - causing said laser beam to ablate said surface area corresponding to each of said first plurality of ablation points;
 - centering said laser beam at a second plurality of ablation points outside of said ablation layer area; and
 - causing said laser beam to ablate said surface area corresponding to each of said second plurality of ablation points.
2. The method of ablating according to claim 1, wherein:
 - said second plurality of ablation points are each within a predetermined distance from a boundary of said ablation layer area.
3. The method of ablating according to claim 2, wherein:
 - said predetermined distance is approximately $\frac{1}{2}$ a distance between adjacent ones of said first plurality of ablation points within said ablation layer area.
4. The method of ablating according to claim 1, wherein:
 - said surface area is an area of corneal tissue.
5. Apparatus for scanning an ablating laser beam across an ablation layer of a surface, comprising:
 - a scanner to move said laser beam in two orthogonal directions across said surface area;

a processor to determine a first plurality of ablation points within said ablation layer, each of said first plurality of ablation points being defined by a center of said laser beam; and

an integrating algorithm in said processor to determine a second plurality of ablation points to be ablated by said laser beam, each of said second plurality of ablation points being defined by a center of said laser beam, and each of said second plurality of ablation points being outside of said ablation layer.

6. The apparatus for scanning said ablating laser beam according to claim 5, wherein:

said integrating algorithm determines said location of said second plurality of ablation points outside of said ablation layer based on a predetermined distance from said ablation layer.

7. The apparatus for scanning said ablating laser beam according to claim 5, wherein:

said integrating algorithm determines said location of said second plurality of ablation points outside of said ablation layer based on a predetermined distance from said ablation layer in either an x or y direction.

8. The apparatus for scanning said ablating laser beam according to claim 7, wherein:

said predetermined distance is approximately $\frac{1}{2}$ a distance between each of said first plurality of ablation points within said ablation layer.

9. The apparatus for scanning said ablating laser beam according to claim 5, wherein:

said surface area is an area of corneal tissue.

10. An apparatus for performing corneal refractive surgery by ablating a portion of a corneal surface of an eye, the apparatus comprising:

a pulsed laser for producing a pulsed output beam;

a scanning mechanism for scanning said pulsed output beam, said pulsed output beam being operatively associated with said scanning mechanism such that said pulsed output beam may be scanned over a predetermined surface of a cornea modeled by a mathematically derived ablation layer curve;

and

a controller operatively associated with said scanning mechanism so as to deliver said pulsed output beam to said predetermined surface of said cornea such that a center point of said pulsed output beam may be disposed for ablation within said ablation layer curve, on said ablation layer curve, and outside of said ablation layer curve.

11. The apparatus according to claim 10, wherein said controller includes:

a microprocessor; and

memory;

said memory containing a representation of an expression:

$n\Delta + F(p,q) - c \leq 0$, where $n\Delta$ is a change in thickness of an n th layer of the corneal surface to be ablated, where $F(p,q) = -Z_{g1}(x(p,q), y(p,q)) + Z_{g2}(x(p,q), y(p,q))$, where Z_{g1} and Z_{g2} define final and initial corneal surfaces, respectively, where c is a constant; and

said scanning mechanism being constructed and arranged to perform a scan such that only output beam center points that satisfy said expression are selected for ablation.

12. The apparatus according to claim 10, wherein said controller includes:

a microprocessor; and

memory, said memory containing a representation of expressions:

$$n\Delta + F(p + \delta, q + \delta) - c \leq 0$$

$$n\Delta + F(p + \delta, q - \delta) - c \leq 0$$

$$n\Delta + F(p - \delta, q + \delta) - c \leq 0$$

$$n\Delta + F(p - \delta, q - \delta) - c \leq 0$$

where $n\Delta$ is a change in thickness of an n th layer of said corneal surface to be ablated, where $F(p, q) = -Z_{g1}(x(p, q), y(p, q)) + Z_{g2}(x(p, q), y(p, q))$, where Z_{g1} and Z_{g2} define final and initial corneal surfaces, respectively, where c is a constant, where p and q represent a first coordinate system, x and y represent a second coordinate system and δ is a constant, and

wherein said scanning mechanism is constructed and arranged to perform a scan such that only output beam center points that satisfy at least one of said expressions are selected during ablation.

13. The apparatus according to claim 12, wherein:

δ is half of a scanning step size.

14. The apparatus according to claim 10 wherein:

said pulsed laser is a UV pulsed laser having an energy level less than 10 mJ/pulse.

15. The apparatus according to claim 14, wherein:

said pulsed laser has an output wavelength between 193 and 220 nanometers.

16. The apparatus according to claim 10, wherein:

said scanning mechanism is constructed and arranged to scan a circular pattern of concentric circles with a center of said circles being non-co-axial with a symmetrical center of said ablation layer curve.

17. The apparatus according to claim 10, wherein:

said scanning mechanism is constructed and arranged to scan a linear pattern of parallel lines of ablation points, wherein a starting point of each parallel line of ablation points is randomly selected with respect to a distance from said ablation layer curve.

18. A method for controlling an apparatus for performing corneal refractive surgery by ablating a portion of a corneal surface of an eye, the apparatus comprising a pulsed laser for producing a pulsed output beam of light; a scanning mechanism for scanning said output beam, said output beam being operatively associated with said scanning mechanism such that said output beam may be scanned over a predetermined surface of a cornea; focusing structure constructed and arranged to focus said output beam onto the predetermined surface to a generally fixed spot size; and a controller operatively associated with the scanning mechanism; the method comprising:

modeling said predetermined surface in the form of a mathematically defined curve;

controlling said scanning mechanism during a scan with said controller so as to deliver output beams to said predetermined surface such that center points of said output beams may be disposed within a boundary defined by said curve, on said boundary of said curve, and at certain locations outside of said boundary of said curve for ablating said predetermined surface substantially corresponding to an area enclosed by said curve.

19. The method according to claim 18, wherein said scanning mechanism is controlled such that only output beam center points that are outside of said boundary of said curve that are a predetermined distance from said boundary are selected during ablation.

20. The method according to claim 19, wherein said curve is modeled in the form of a generally oval shape.

21. The method according to claim 18, wherein said scanning mechanism is controlled by an expression: $n\Delta + F(p,q) - c \leq 0$, where $n\Delta$ is a change in thickness of an n th layer of the corneal surface to be ablated, where $F(p,q) = -Z_{g1}(x(p,q), y(p,q)) + Z_{g2}(x(p,q), y(p,q))$, where Z_{g1} and Z_{g2} define final and initial corneal surfaces, respectively, and where c is a constant, and

wherein the scanning mechanism performs a scan along a p -

axis of said curve and a q -axis that is orthogonal to the p -axis, and wherein x and y represent x and y axis, respectively, such that only output beam center points that satisfy said expression are selected during ablation.

22. The method according to claim 18, wherein said scanning mechanism

is controlled by expressions:

$$n\Delta + F(p + \delta, q + \delta) - c \leq 0$$

$$n\Delta + F(p + \delta, q - \delta) - c \leq 0$$

$$n\Delta + F(p - \delta, q + \delta) - c \leq 0$$

$$n\Delta + F(p - \delta, q - \delta) - c \leq 0$$

where $n\Delta$ is a change in thickness of an n th layer of the corneal surface to be ablated, where $F(p, q) = -Z_{g1}(x(p, q), y(p, q)) + Z_{g2}(x(p, q), y(p, q))$, where Z_{g1} and Z_{g2} define final and initial corneal surfaces, respectively, and where c is a constant, and

wherein the scanning mechanism performs a scan along a p -axis and a q -axis that is orthogonal to the p -axis of said curve and wherein x and y represent the x and y axis, respectively, and wherein δ is a constant, such that only output beam center points that satisfy at least one of said expressions are included in ablation.

23. The method according to claim 18, wherein said scanning mechanism scans a circular pattern of concentric output beam spots, wherein a center of said circular pattern is placed randomly on said

predetermined surface.

24. The method according to claim 18, wherein said scanning mechanism scans a linear pattern of output beam spots, wherein a starting point of each line of said liner pattern is randomly selected.

1/6

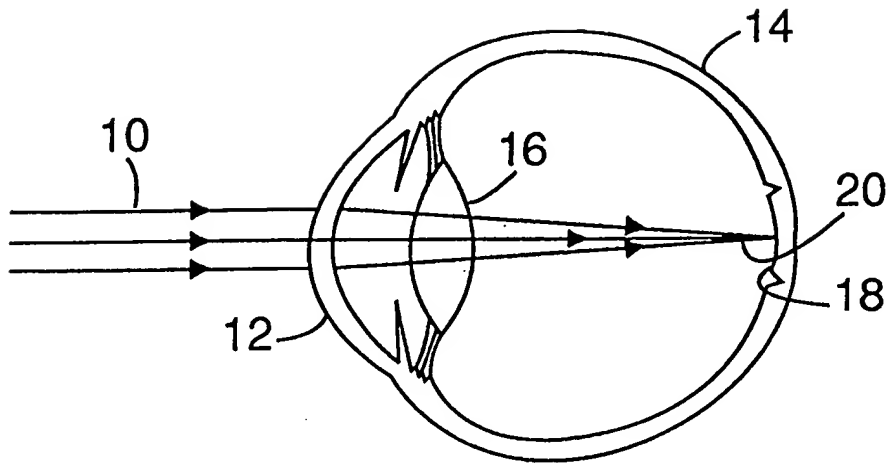


FIG. 1 PRIOR ART

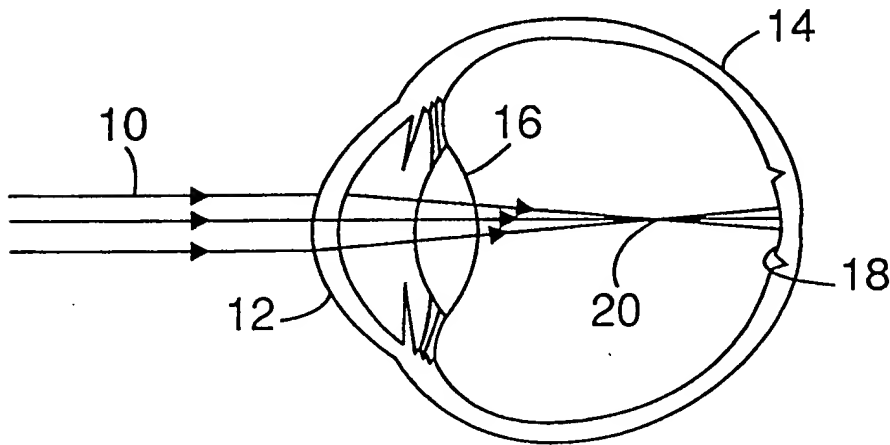


FIG. 2 PRIOR ART

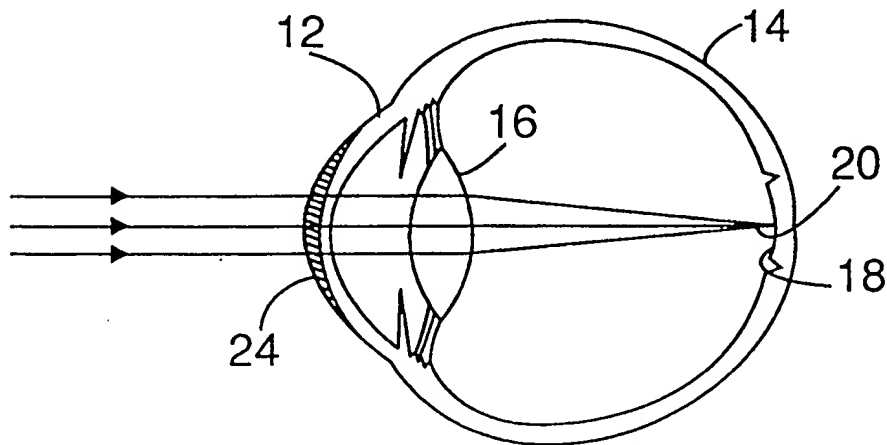
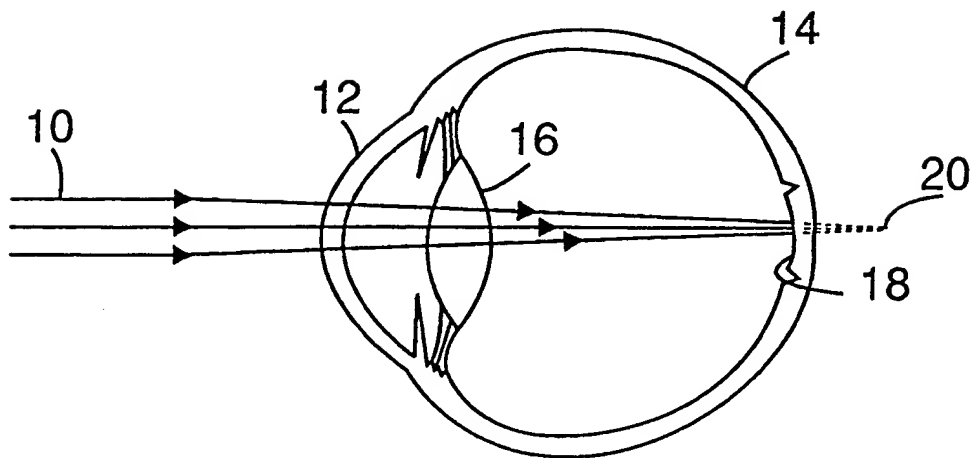
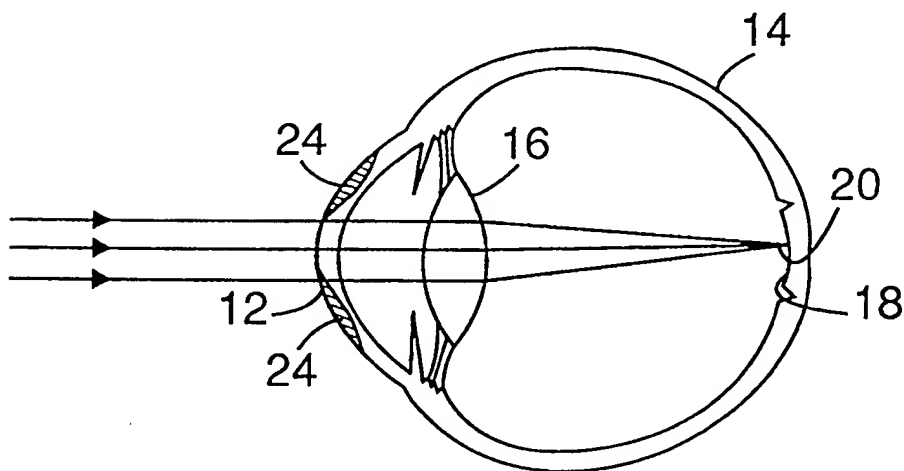
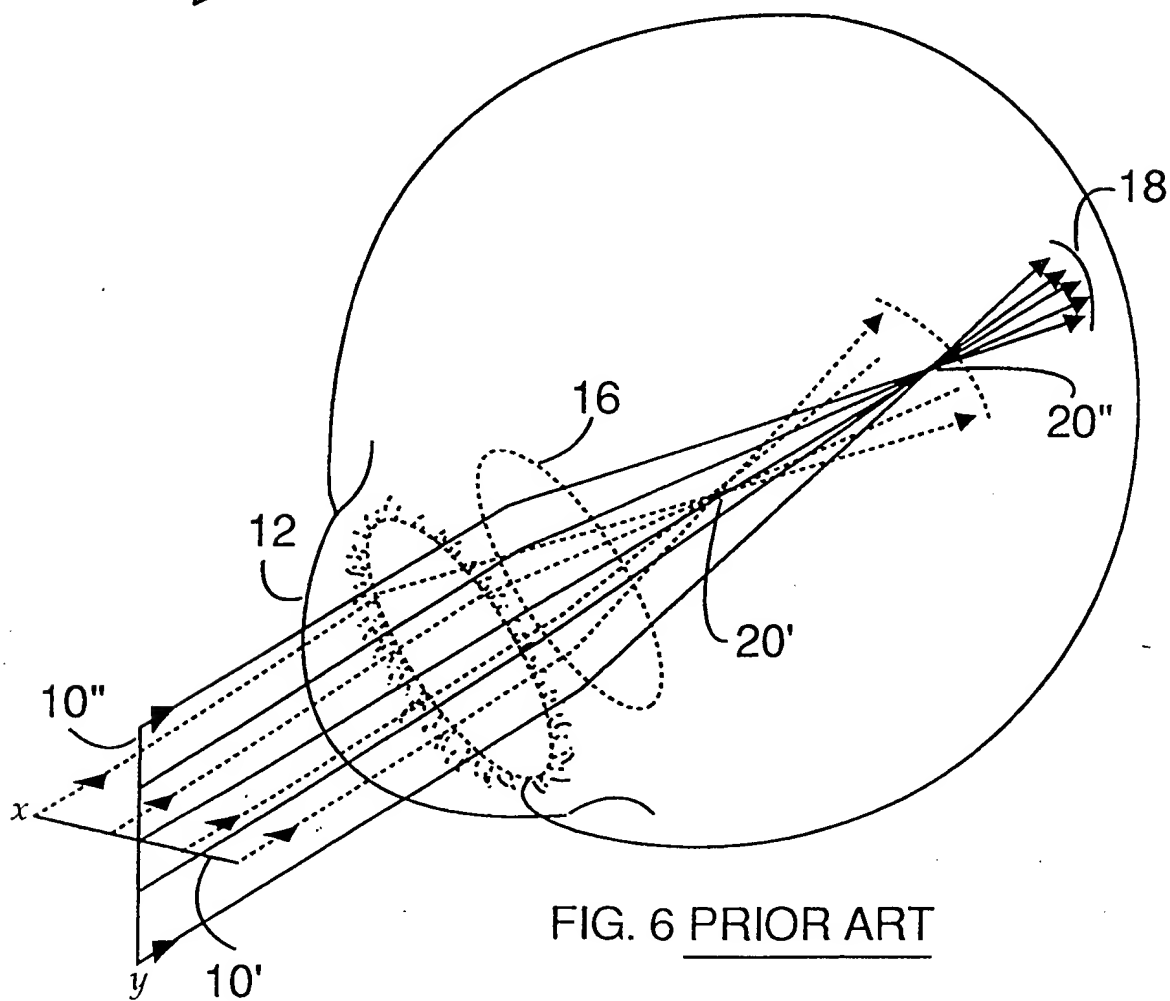
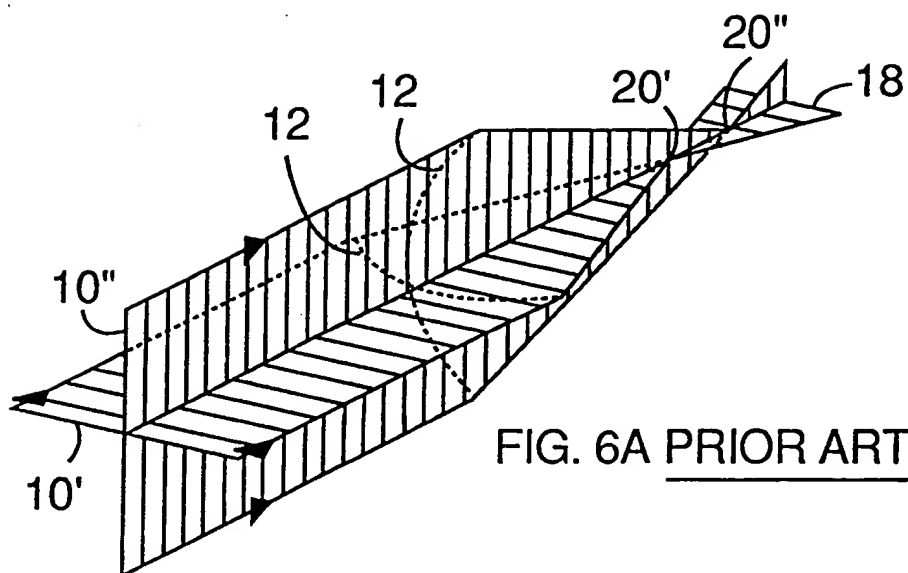


FIG. 3 PRIOR ART

2/6

FIG. 4 PRIOR ARTFIG. 5 PRIOR ART

3/6



4/6

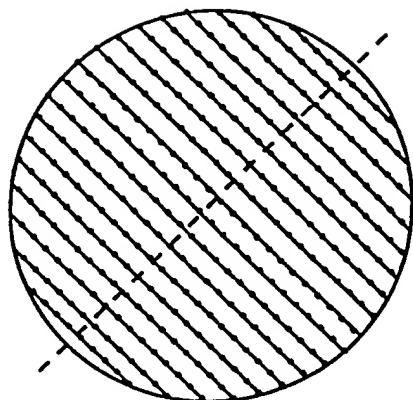


FIG. 7A PRIOR ART

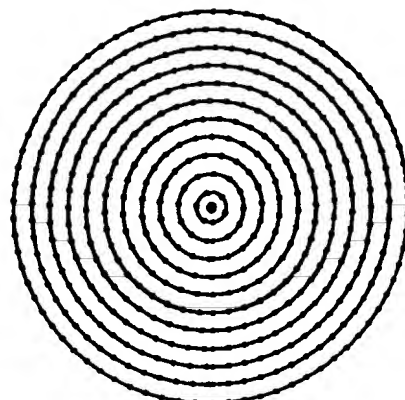


FIG. 7B PRIOR ART

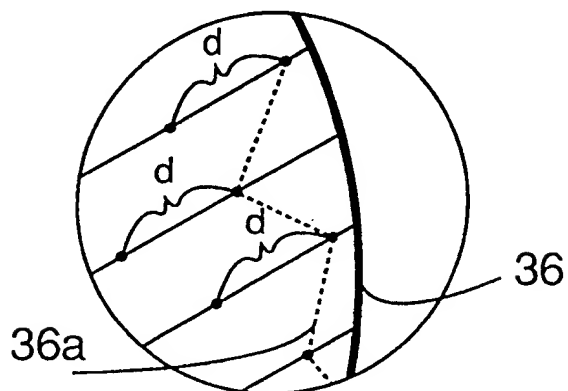


FIG. 8A (1) PRIOR ART

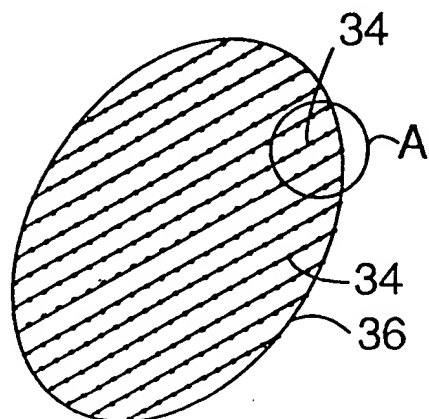


FIG. 8A PRIOR ART

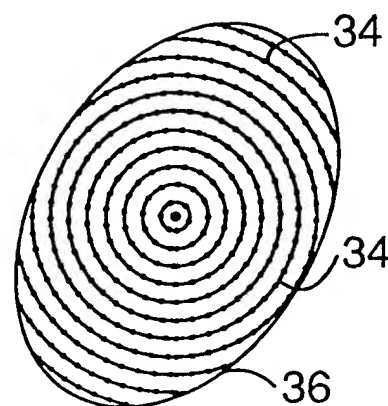


FIG. 8B PRIOR ART

5/6

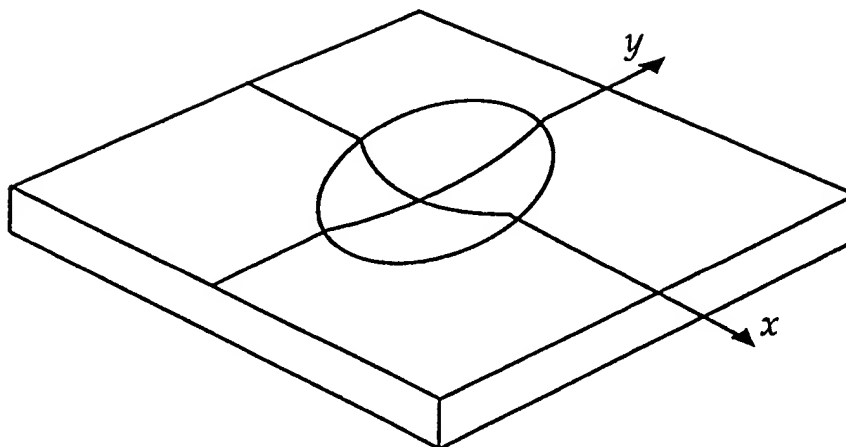


FIG. 11 PRIOR ART

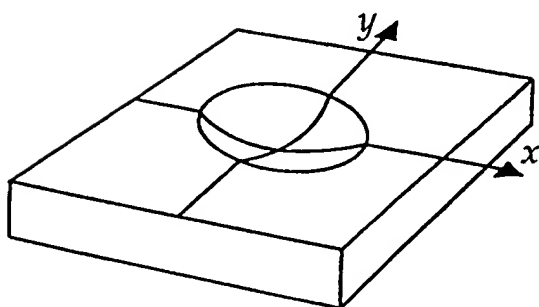


FIG. 9 PRIOR ART

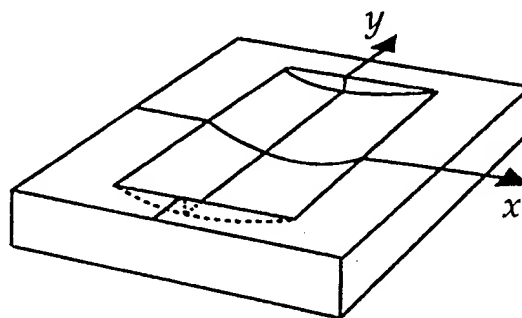


FIG. 10 PRIOR ART

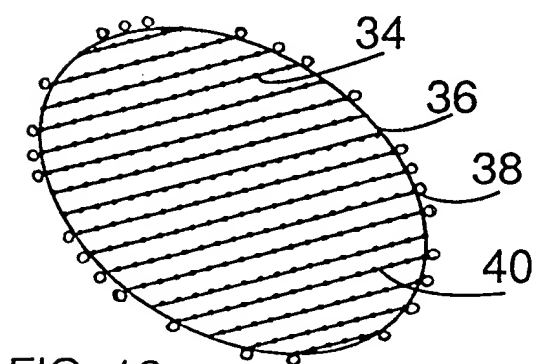


FIG. 12

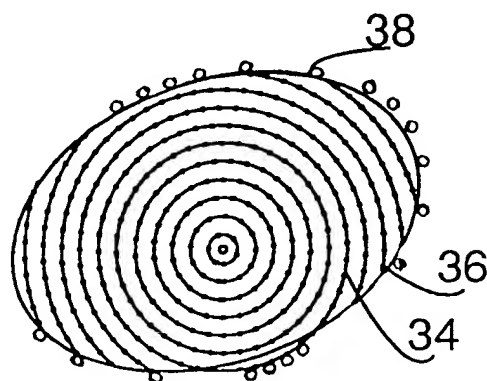


FIG. 13

6/6

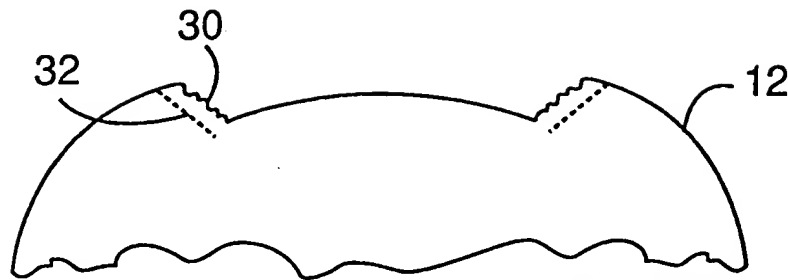
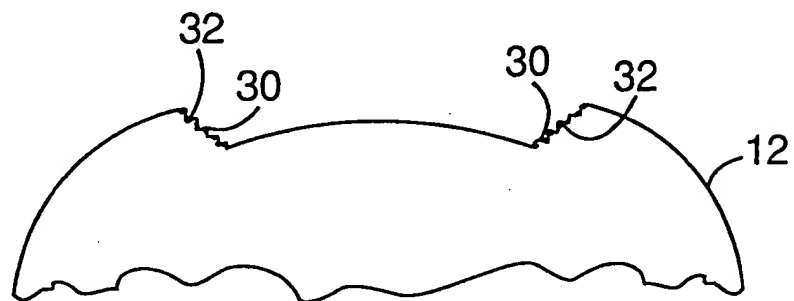
FIG. 15 PRIOR ART

FIG. 16

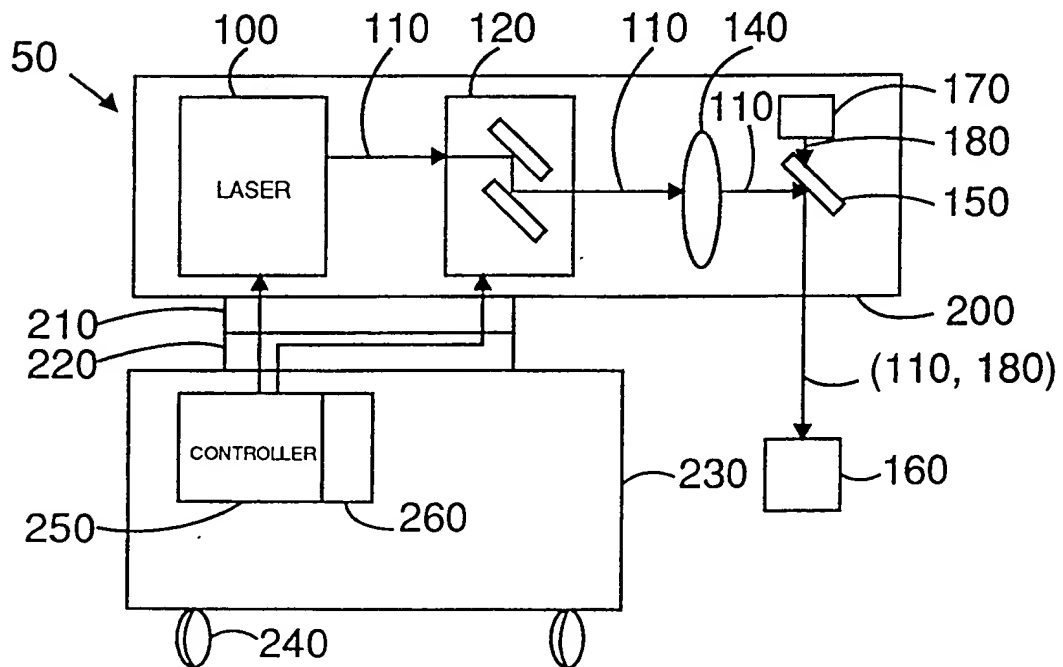


FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/19241

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/02

US CL :219/121.73; 606/5, 11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 219/121.60, 121.68, 121.69, 121.73-121.8; 606/4-6, 10-13, 17-19

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,848,104 A (LOCKE) 12 November 1974. entire document.	1-24
Y	US 5,284,477 A (HANNA et al.) 08 February 1994. entire document.	1-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

03 JANUARY 1998

Date of mailing of the international search report

05 FEB 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DAVID SHAY

Telephone No. (703) 308-2215